

**REMARKS**

By this Amendment, Applicant amends claim 1 for a minor informality and adds new dependent claim 28. The originally filed specification, claims, abstract, and drawings fully support the subject matter of amended claim 1 and new claim 28. No new matter has been introduced. Accordingly, claims 1-7 and 9-28 remain pending in this application.

As an initial matter, the Applicant would like to thank the Examiner for indicating the allowance of claims 9-21. In addition, the Applicant would like to thank the Examiner for indicating that claims 5-7 and 22-27 contain allowable subject matter. Applicant, however, would like to keep claims 5-7 and 22-27 in dependent form.

On page 2 of the Office Action, the Examiner rejected claims 1-4 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,620,194 to Ding et al. (“Ding”) in view of U.S. 6,258,121 to Yang et al. (“Yang”). Applicant respectfully traverses the rejection for at least the following reasons.

Ding discloses a biostable coating 102 containing a biologically active material coated onto the surface of a deployable metal stent 101. See Col. 3, line 66, through Col. 4, line 4 of Ding. Specifically, Ding discloses a stent 101 having a coating 102 composed of a thin topcoat 104 coated over an undercoat 103. Large drug particles 106 having a thickness greater than the topcoat 104, may be released from undercoat 103 upon exposure to bodily fluids. See Col. 13, lines 43-53 of Ding.

Yang discloses a stent 10 or 110 having a polymeric coating 30 including an active agent. See Col. 2, lines 38-41 of Yang. The stent 10 or 110 is composed of a biocompatible material, including either metallic or polymeric materials. Yang further

discloses that the polymeric coating 30 includes a blend of a polymers that may be adjusted to higher or lower degradation rates to achieve a desired release rate of the active agent. See Col. 4, lines 50-65 of Yang.

In contrast, claim 1 recites a “fastener”. Neither Ding nor Yang discloses a fastener. In particular, Ding and Yang both disclose stents. Those skilled in the art recognize that a stent is not a fastener.

Furthermore, neither reference teaches the features described in new dependent claim 28. In particular, dependent claim 28 recites a biocompatible fastener “wherein said pair of members are configured to fasten together two or more biological materials.” Neither Ding nor Yang discloses, teaches, or suggests a device fastening together two or more biological materials.

Even assuming *arguendo* that the stents of Ding and Yang are a “fastener”, which the Applicant does not necessarily concede, the modification of Ding in view of Yang is impermissible for the additional reasons set forth below.

Ding specifically teaches that polymeric stents have inferior mechanical properties compared to metal stents of similar weave and thickness. Ding further teaches that polymeric stents may be altered to provide comparable strength, however these stents are required to have either a dense filament weave or a thick-walled structure which reduces the cross-sectional area for fluid transport. See Col. 3 lines 1-10 of Ding. Ding therefore disparages the use of polymeric stents relative to metal stents. Ding then teaches that its coating 102 on a metal stent is important, as it obviates the need for a thick polymer stent. Specifically, Ding states:

It will be appreciated that the mechanism of incorporation of the biologically active species into a thin

surface coating structure applicable to a *metal stent* is an important aspect of the present invention. The need for relatively thick-walled polymer elution stents or any membrane overlayers associated with many prior drug elution devices is obviated, as is the need for utilizing biodegradable or reabsorbable vehicles for carrying the biologically active species (emphasis added).

See Col. 15 lines 1-8 of Ding.

The Office Action nonetheless asserts that “[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made, to modify the inner core of the device of Ding et al., in view of Yang et al., so that it is formed [of] a second bioabsorbable material having a slower degradation rate than the first bioabsorbable material.” See page 3 of the Office Action. In other words, the Office Action modifies stent 101 to comprise of a polymeric material. Such a modification, however, would lead to a decrease in either the mechanical or therapeutic benefit of the stent, and squarely leads away from the very disclosure of Ding. A modification that renders the stent unsatisfactory for its intended purpose, i.e., unsatisfactory for providing vessel or lumen wall support for the purpose of preventing restenosis, establishes that there is no suggestion or motivation to make the proposed modification. See MPEP 2143.01 V. Moreover, according to the M.P.E.P and federal case law, prior art that teaches away from a claimed invention cannot be combined with a reference teaching that aspect to render the claimed invention obvious. See M.P.E.P. § 2141.02 VI citing W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983).

Accordingly, Applicant submits independent claim 1 is allowable for at least these reasons. Additionally, rejected claims 2-4, objected claims 5-7 and 22-27, and new

claim 28 depend from claim 1 and are allowable for at least this reason as well as for their additional features.

The Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicant declines to subscribe to any statement or characterization in the Office Action.

In view of the foregoing remarks, the Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

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By: \_\_\_\_\_

  
Leslie I. Bookoff  
Reg. No. 38,084  
(202) 408-4000